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FEB 16 2000

K000159

Summary of Safety and Effectiveness
Special 510(k) : Device Modification

Full Leg / Full Spine Image Stitching Software
For ADC Compact Computed Radiography System

DEVICE NAME	Full Leg / Full Spine Image Stitching Software	
CLASSIFICATION NAME:	Phosphor Plate Radiographic System - 21CFR 892.1630 This device has been categorized as 90IXK and is regulated as Class II	
TRADE/PROPRIETARY NAME:	Agfa Diagnostic Center or ADC Compact	
SUBMITTED BY	Agfa Corporation 10 South Academy Street Greenville, SC 29601	864-421-1600
CONTACT PERSON	Timothy W. Capehart	864-421-1834

PERFORMANCE STANDARDS:

The device complies with the relevant international and national Safety Standards. It has been manufactured in compliance with ISO9000 and the Quality System Regulation.

DESCRIPTION OF MODIFICATION:

The ADC Full leg/full spine software automates the process of forming a geometrically accurate full-body image with as little user action as possible. Images are obtained by the use of several overlapping ADC plates in several ADC cassettes in a specially-built cassette-holder. This full-body cassette-holder minimizes manual handling.

The sub-images are combined into a single image with the help of grid lines to ensure accurate alignment. The ADC Full Leg/Full Spine application compensates for various sources of misalignment such as overlap, shift, rotation and perspective foreshortening. The newly composed image is available for PACS and ready for operations such as MUSICA, enlargement of specific image portions, annotation, analyzing and angle measurements, printing, and so on...

Orthopedic clinicians will benefit from this application software in areas such as the assessment of scoliosis. Potential applications include, for instance: accurate measurement of spine angles and distances between anatomic entities, assessment of the evolution of therapy over time and identification of orthopedic surgery indications.

The system modification is comprised of the software upgrade and the cassette holder.

EQUIVALENCE INFORMATION:

The ADC was cleared for market on 9 March 1990. The device is being modified at this time with the addition of a software module and hardware accessory to be used with the software. The purpose of these modifications is to facilitate the use of multiple cassettes to capture long anatomical structures such as limbs and spines and then assemble the component images into a single image to facilitate review. Cassettes and radiographic techniques will remain unchanged. The intended use of the device, previously stated as "To provide diagnostic quality images for aid in physician diagnosis," remains unchanged. Applications for imaging the Chest and Skeleton are also previously cleared. The modification does not affect the intended use of the device or alter the fundamental scientific technology of the device.

Design control requirements are in place within Agfa and require verification and validation studies. For this reason, Agfa is electing to utilize an alternative method of demonstrating substantial equivalence, Special 510(k) for Device Modification," for the device modification identified as "Full Leg/Full Spine Image Stitching". Agfa contends that design controls in place provide a basis for the substantial equivalence determination.

SAFETY INFORMATION:

This device is identical to the predicate and has identical safety issues and concerns. A summary of the software design description, hazard analysis, and technical and safety information can be found in the attached submission. The results of the hazard analysis, combined with the appropriate measures taken during design and development indicate the device is of minor level of concern, as per the August 29, 1991 issue of the "*Reviewers Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review*".

Only trained professionals utilize the device and evaluate its output. This allows sufficient review to afford identification and intervention in the event of a malfunction. The device impacts the quality or status of the original acquired image data only in the validated manner described.

Agfa Corporation feels that sufficient information and data are contained in this submission to enable CDRH to reach a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 2000

Timothy W. Capehart
Manager of Regulatory Affairs and Compliance
AGFA Corp.
10 South Academy St.
Greenville, SC 29601

Re: K000159
Full Leg/Full Spine Image Stitching Software for
ADC Compact Computed Radiography System
Dated: January 17, 2000
Received: January 19, 2000
Regulatory class: II
21 CFR 892.1630/Procode: 90 IXK

Dear Mr. Capehart:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

K000159

510(k) Number (if known) : K000159

Device Name : Full Leg/Full Spine Image Stitching Software
For ADC Compact Computed Radiography System

Indications for Use:

To provide diagnostic quality images to aid the physician in diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000159

Prescription Use X
(Per 21 CFR 801.109)

Over the Counter Use _____